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UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

Ronald L. Wilson, Director Health Assessment Policy Staff Office of Health Affairs (HFY-20) Food and Drug Administration 5600 Fishers Lane, Room 15-22 Re: REDUX™
FDA Docket No. 96E-0265

Dear Mr. Wilson:

Rockville, MD 20857

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,309,445, which issued January 5, 1982. The application was filed on June 25, 1996, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Telephone inquiries regarding this matter should be directed to the undersigned at (703)306-3159.

Karin Tyson

Legal Advisor

Special Program Law Office

Office of the Deputy Assistant Commissioner

for Patent Policy and Projects

cc: Charles E. Van Horn

Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.

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